K062610

510(k) Summary of Safety and Effectiveness

SEP 28 2006

Date:	June 5, 2006
Submitter:	Ohio Medical Corporation 1111 Lakeside Drive Gurnee, IL 60031
Contact Person:	Hoby Chae Director of Engineering & Quality Ohio Medical Corporation 847-855-6272 847-855-6304 (fax)
Device: Trade Name:	care-e-vac 3
Common/Usual Name:	Portable medical suction device
Classification Names:	
CFR Reference:	21CFR878.4780
Classification Name:	Pump, Portable, Aspiration
Product Code:	BTA
Predicate Device:	K926566 - Care-E-Vac II
Device Description:	The device uses conventional technology to provide medical suction. The mechanical portion of the aspirator consists of an electrically driven pump to provide suction, a gauge to indicate the suction level and a regulator to control the suction level.
Intended Use:	The device is a portable aspirator which uses suction as a means to withdraw fluids or foreign bodies from a patient. The primary intended use of the care-e-vac 3 is as an aspirator to be used to help evacuate saliva, mucous, vomitous or other aspirant from the mouth and or airway to allow adequate respiration or ventilation of the patient.
Technology:	The care-e-vac 3 employs the same functional technology as the predicate device.
Test Summary:	The care-e-vac 3 complies with the voluntary standards as detailed in Section 9 of this submission.
Conclusion:	The results of these measurements demonstrated that the care-e-vac 3 is as safe, as effective, and performs as well as the predicate device.

Section 3 Proposed Labeling

3.1 Intended Use

The device is a portable aspirator which uses suction as a means to withdraw fluids or foreign bodies from a patient. The primary intended use of the care-e-vac 3 is as an aspirator to be used to help evacuate saliva, mucous, vomit or other aspirant from the mouth and or airway to allow adequate respiration or ventilation of the patient.

The intended use has not changed as a result of changes to the care-e-vac 3.

3.2 Proposed Operating Instructions

Refer to Appendix A for a copy of changes made to the care-e-vac 3 Operator's Manual due to the device modifications contained in this release.

3.3 Promotional Material / Specification Sheet

A draft promotional brochure / specification sheet for the care-e-vac 3 can be found in Appendix B.

3.4 Device and Package Labeling

Draft device and package labeling for the care-e-vac 3 can be found in Appendix E.

Reference the following documents:

	Appendix
Operating Instructions	A
Promotional Brochure / Specification Sheet	B
Label – Example	E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2006

Mr. Hoby Chae
Director of Engineering and Quality
Ohio Medical Corporation
1111 Lakeside Drive
Gurnee, Illinois 60031

Re: K062610
Trade/Device Name: CARE-E-VAC 3
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: BTA
Dated: August 30, 2006
Received: September 5, 2006

Dear Mr. Chae:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

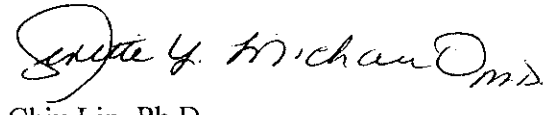
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: care-e-vac 3

Indications For Use:

The device is a portable aspirator which uses suction as a means to withdraw fluids or foreign bodies from a patient. The primary intended use of the care-e-vac 3 is as an aspirator to be used to help evacuate saliva, mucous, vomit or other aspirant from the mouth and or airway to allow adequate respiration or ventilation of the patient.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices
...) Number: K062610